(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
18 January 2001 (18.01.2001)

PCT

(10) International Publication Number
WO 01/03667 A1

(51) International Patent Classification[7]: A61K 9/113, 47/48, 48/00, 9/16

(21) International Application Number: PCT/EP00/06460

(22) International Filing Date: 7 July 2000 (07.07.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
99113251.5 8 July 1999 (08.07.1999) EP
00101030.5 20 January 2000 (20.01.2000) EP

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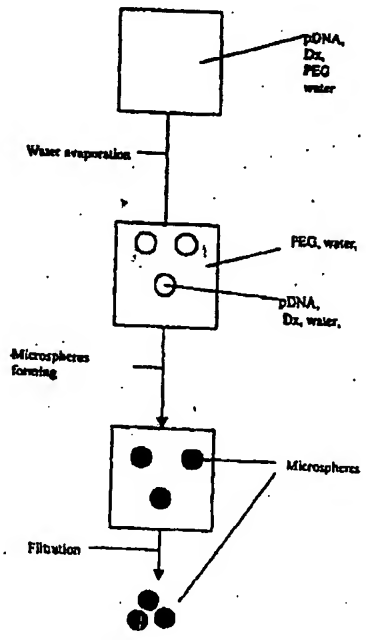
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *With international search report.*
— *Before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments.*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: DELIVERY SYSTEM FOR BIOLOGICAL MATERIAL



(57) Abstract: The present invention relates to a composition and method for delivery of biological material, especially nucleic acids into target cells and into the nucleus.

WO 01/03667 A1

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

KÖNIG,Reimar; PALGEN,Peter;
SCHUHMACHER, Horst; KLUIN,
Jörg-Eden; KÖNIG, Gregor
Lohengrinstrasse 11
40549 Düsseldorf
ALLEMAGNE

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Rule 71.1)

Applicant's or agent's file reference 43 709 K	Date of mailing *(day/month/year)* 09.11.2001
	IMPORTANT NOTIFICATION
International application No. PCT/EP00/06460	International filing date *(day/month/year)* 07/07/2000
	Priority date *(day/month/year)* 08/07/1999
Applicant HILGERS, Arnold	

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/	Authorized officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Hutterer, G Tel.+49 89 2399-8066

Form PCT/IPEA/416 (July 1992)

PA NT COOPERATION TREAT

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
US Department of Commerce
United States Patent and Trademark Office, PCT
2011 South Clark Place Room CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 13 March 2001 (13.03.01)	
International application No. PCT/EP00/06460	**Applicant's or agent's file reference** 43 305K
International filing date (day/month/year) 07 July 2000 (07.07.00)	**Priority date** (day/month/year) 08 July 1999 (08.07.99)
Applicant HILGERS, Arnold	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

27 January 2001 (27.01.01)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer Juan Cruz
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

Form PCT/IB/331 (July 1992)

Translation

10/018723

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference Anm.99/003WO	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP00/05878	International filing date (*day/month/year*) 26 June 2000 (26.06.00)	Priority date (*day/month/year*) 29 June 1999 (29.06.99)
International Patent Classification (IPC) or national classification and IPC C12N 15/12, C07K 14/47, C12N 15/63, A01K 67/027, C07K 16/18, G01N 33/68, A61K 48/00, 38/17, 39/395, C12Q 1/68		
Applicant MULTIGENE BIOTECH GMBH		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 22 January 2001 (22.01.01)	Date of completion of this report 26 September 2001 (26.09.2001)
Name and mailing address of the IPEA/EP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/EP00/05878

I. Basis of the report

1. With regard to the **elements** of the international application:*

☐ the international application as originally filed

☒ the description:

pages 1-17, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the claims:

pages 1-22, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the drawings:

pages 1/7-7/7, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the sequence listing part of the description:

pages _____, as originally filed
pages _____, filed with the demand
pages 1-15, filed with the letter of 14 November 2000 (14.11.2000)

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☒ furnished subsequently to this Authority in written form.
☒ furnished subsequently to this Authority in computer readable form.
☒ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/EP00/05878

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 16, 17(f), and 18-22

because:

☒ the said international application, or the said claims Nos. 18-22 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

See supplemental sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 16, 17(f).

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III.

1. Claims 18-22 relate to a subject matter that, in the opinion of this Examining Authority, falls under PCT Rule 67.1(iv). Therefore, a report will not be made about the industrial applicability of the subject matter of these claims (PCT Article 34(4)(a)(i)).

V. **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	5-7, 12-15, 17-22	YES
	Claims	1-4, 8-11	NO
Inventive step (IS)	Claims		YES
	Claims	1-15, 17-22	NO
Industrial applicability (IA)	Claims	1-15, 17	YES
	Claims		NO

2. Citations and explanations

Reference is made to the following document:

D1 = DATABASE EMBL; Entry AF151813, 1 June 1999; LIN W.-C.: "Homo sapiens CGI-55 protein mRNA, complete cds."

1. The present application relates to nucleic acid for two interactors (FANCIP2 and FANCIP3) of the Fanconi anemia protein of the complementation group A, corresponding proteins, analogues, fragments and applications thereof.

1.1 Document D1, which is the closest prior art discloses a nucleic acid molecule that shows 99% homology to 800 nucleotides from the nucleotide sequence shown in Figure 1. The corresponding protein shows 99.5% homology to the aminoacid sequence shown in
Figure 2. The subject mater of Claims 1-4 and 8-11 is thus not novel (PCT Article 33(2)).

1.2 Dependent Claims 5-7, 12-15 and 17-22 are novel and satisfy the requirements of PCT Article 33(2). Nonetheless, those claims only relate to common

embodiments such as vectors, transformed cells, antibodies, pharmaceutical compounds or processes for identifying effectors and appear to contain no additional features that, combined with the features of any claim to which Claims 5-7, 12-15 and 17-22 refer, could lead to a subject matter involving an inventive step. The subject matter of Claims 5-7, 12-15 and 17-22 thus does not involve an inventive step under PCT Article 33(3).

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

1. Claims 1 and 9 contain references to the drawings. According to PCT Rule 6.2(a), claims can only contain references if absolutely necessary, which is not the present case.

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. The expressions "segment" and "fragment" used in Claims 1, 3, 5 and 13 are vague and unclear and leave the reader uncertain as to the meaning of the related technical features. Consequently, the definition of the subject matter of these claims is unclear (PCT Article 6).

2. The applicant should note that the expression "preferably" in Claim 2 does not delimit the scope of protection of the claims, i.e., that which follows such a feature is considered to be entirely optional.

3. The term "modified" used in Claims 4 and 11 is vague and unclear and leaves the reader uncertain as to the meaning of the related technical features. Consequently, the definition of the subject matter of these claims is unclear (PCT Article 6).

4. The term "analogue" used in Claims 4 and 11 is vague and unclear and leaves the reader uncertain as to the meaning of the related technical features. Consequently, the definition of the subject matter of these claims is unclear (PCT Article 6).

5. Claim 7 does not satisfy the requirements of PCT Article 6 because the subject matter of the claim is not clearly defined. This claim attempts to define its subject matter in terms of the result to be achieved ("the corresponding natural gene of which was selectively destroyed") and in doing so merely

VIII. Certain observations on the international application

states the problem addressed. To remedy this defect, the technical features necessary for achieving that result should be included in the claim.

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
43 709 K		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP00/06460	07/07/2000	08/07/1999
International Patent Classification (IPC) or national classification and IPC A61K9/113		
Applicant HILGERS, Arnold		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 5 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
27/01/2001	09.11.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Vermeulen, S Telephone No. +49 89 2399 7520

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP00/06460

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1-23	as originally filed				

Claims, No.:

1-36	with telefax of	24/10/2001			

Drawings, sheets:

1	as received on	10/10/2000	with letter of	09/10/2000	

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   - ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   - ☐ the language of publication of the international application (under Rule 48.3(b)).
   - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   - ☐ contained in the international application in written form.
   - ☐ filed together with the international application in computer readable form.
   - ☐ furnished subsequently to this Authority in written form.
   - ☐ furnished subsequently to this Authority in computer readable form.
   - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   - ☐ the description, pages:
   - ☐ the claims, Nos.:

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	6,15-19,22,23,25-33
	No:	Claims	1-5,7-14,20,21,24,34-36
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-36
Industrial applicability (IA)	Yes:	Claims	1-36
	No:	Claims	

2. Citations and explanations
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: US-A-5 849 884 (WOISZWILLO ET AL.) 15 December 1998 (1998-12-15)
D2: EP-A-0 842 657 (OCTOPLUS B.V.) 20 May 1998 (1998-05-20)
D3: EP-A-0 213 303 (MAGNUS ET AL.) 11 March 1987 (1987-03-11)

NOVELTY

The composition as defined in claim 1 is a two-phase aqueous polymer system comprising (i) biological material, (ii) at least two compounds leading to spontaneous formation of a dispersed phase and (iii) microparticles in the dispersed phase. Said composition is not novel (Art. 33(2)PCT) since **D1 (column 3, line 21 - column 4, line 5 ; examples)**, **D2 (page 3, lines 29-54 ; page 4, lines 14-48 ; examples)** and **D3 (whole document)** disclose compositions falling within the definition of claim 1.

The subject-matter of claim 1 is partially defined as a product-by-process. Whether the formation of the dispersed phase however occured spontaneous or not is of little significance in the present composition claim, since this can not be checked. Aqueous solutions of two incompatible polymers will spontaneously separate into a dispersed and continuous phase when a critical polymer concentration has been reached e.g. by evaporation of water. On the other hand, when two incompatible polymer solutions are mixed in such a way that the concentration in the final mixture is already above the critical concentration (cf. **D1, D2** and **D3**), mechanical energy (e.g. vortexing, stirring) should be put into the system in order to get a finely dispersed phase. This mechanical energy is in fact implicitely provided when mixing both solutions. The resulting two-phase compositions however cannot be distinguished from spontaneously formed two-phase compositions, i.e. starting from a one-phase solution containing both polymers.

Although **D1** teaches the use of conventional emulsification means, like stirring, vortexing and sonication, spontaneous formation of a dispersed phase is not excluded: the formation of microparticles can also be observed just by heating one-phase aqueous solutions of incompatible polymers, e.g. **example 14**.

In view of **D1-D3** dependent claims 2-5, 7-14, 20-21 and 24 as well as independent claim 34 do not appear to contain any additional subject-matter which meets the novelty requirement of the PCT (Art. 33(2)).

Refering to the above raised novelty objection concerning the composition (cf. claim 1) leading to microparticles, the subject-matter of claims 35-36 cannot be novel as well.

INVENTIVE STEP

Claims 25-33 define a method for preparation of microparticles. Said method meets the novelty requirement of the PCT. However, in view of document **D1-D3**, the claimed method lacks an inventive step (Art. 33(3) PCT).

The method for preparing microparticles in **D3** is similar to the method proposed in the present application, the only difference being the fact that in **D3** the two-polymer system is emulsified by mechanical means (stirring), since from the start the two incompatible polymers are mixed in a concentration which does not allow the formation of a solution anymore, i.e. a dispersed phase is formed from the beginning, whereafter the emulsion is further concentrated by removing water in order to make the dispersed phase (liquid droplets) turn into solid microparticles. The removing of water can be performed by evaporation **(D3: column 3, lines 33-42)**. Compared to **D1-D3**, the method of the present application starts from a one-phase solution of two polymers, which is further concentrated using evaporation, in order to obtain a phase separation (formation of a dispersed phase) followed by the formation of microparticles. The concentration step leading to the phase separation is superfluous in **D1-D3** since at the time of mixing the polymers are already present in a concentration sufficiently high to cause phase separation. The introduction of such an additional concentration step however is not regarded as involving an inventive step since it is obvious to a man skilled in the art.

According to the general teaching of prior art documents **D1-D3**, the subject-matter as defined in the present claims 1-36 does not appear to contain any features which may meet the requirements of the PCT with regard to inventive step (Art. 33(3)).

INDUSTRIAL APPLICABILITY

The subject-matter of claims 1-36 meets the requirements of Art.33(4) PCT.

Re Item VIII

Certain observations on the international application

Claims 15-16, 20, 24, 26-33:

The subject-matter of said claims is not disclosed in the description.

Description (pages 11-12)

For the detailed disclosure of the "invention", references are made to "prior art" documents (cf. Reference 10, 11, 12). This is somewhat confusing. *Remark*: on page 12 (line 3) the "Ref.11" should probably read "Ref.12".

KÖNIG · PALGEN · SCHUMACHER · KLUIN

PATENTANWÄLTE

DÜSSELDORF · ESSEN

PCT/EP00/06460

24. October 2001
43 709 K

"Delivery system for biological material"

Claims:

1. A composition to produce particles for delivery of biological material into a target cell comprising:

   biological material,
   a preparation of an aqueous polymer system on the basis of a mixture with at least two compounds being incompatible in aqueous solutions,
   said compounds being present in a concentration in water that leads to the spontaneous formation of a dispersed phase by one of said compounds,
   said dispersed phase including microparticles in said aqueous solution.

2. A composition according to claim 1, wherein the mixture is a water mixture.

3. A composition according to claims 1 or 2, wherein first and second compounds are carbohydrate-based polymers or derivatives thereof.

4. A composition according to claims 1 or 2, wherein first compound is a carbohydrate-based polymer or derivative thereof and second compound is a polyaliphatic alcohol or derivative thereof.

5. A composition according to one of the claims 1 to 4, wherein the carbohydrate-based polymer is dextran, or dextrin, or a methylcellulose based polymer, or a carboxymethyl cellulose-based polymer, or polydextrose, or chitin, or chitosan, and/or starch, or hetastarch, or Ficoll, or derivatives thereof, or naturally occurring polymers as zein, and pullulan, or derivatives thereof.

6. A composition according to claim 5, wherein one compound is substituted by a nucleic acid-binding agent.

7. A composition according to one of the claims 4 to 6, wherein the polyaliphatic alcohol is polyethylene oxide, or a derivative thereof, or polyethylene glycol (PEG), or PEG-acrylate, or polyvinyl acetate, or a derivative thereof.

8. A composition according to claim 7, wherein said is polyethyleneglycol has a molecular weight from 3 kDa to 20 kDa.

9. A composition according to one of the above claims, said composition comprising a surfactant or a derivative thereof.

10. A composition according to claim 9, wherein said surfactant is polyoxyethylene sorbitan and fat acid ether (Tween-20,40,60,80).

11. A composition according to one of the above claims, said composition comprising polyoxyethylene-polyoxypropylene co-polymer.

12. A composition according to claim 11, wherein said polyoxyethylene-polyoxypropylene co-polymer is Pluronic L-64 or Pluronic F-68, or a derivative thereof.

13. A composition according to one of the above claims, said composition comprising polyvinylpyrrolidone (PVP).

14. A composition according to one of the above claims, wherein said biological material comprises polynucleotides, or vaccines (microbes, viruses) or proteins, or peptides, or derivatives thereof.

15. A composition according to one of the above claims, wherein said biological material comprises cytokines or monoclonal antibodies

16. A composition according to claim 15, wherein said cytokines comprise interferones and/or interleukines.

17. A composition according to claim 6, wherein said nucleic acid-binding agent is a peptide or a protein.

18. A composition according to claim 17, wherein said peptide are low molecular weight polylysines or polyethylenimines or derivatives thereof.

19. A composition according to claim 17, wherein said protein is a histone.

20. A composition according to claim 5, wherein said dextran has a molecular weight from 4 kDa to 5000 kDa.

21. A composition according to claim 14, wherein said polynucleotide is DNA.

22. A composition according to claim 14, wherein said polynucleotide is RNA.

23. A composition according to claim 22, wherein said RNA is antisense.

24. A composition according to claim 7, wherein said is polyethylene glycol has a molecular weight from 1 kDa to 20 kDa.

25. A method for preparation of microparticles with use of a composition according to one of the above claims, wherein the concentration of water for formation of microparticles is achieved by evaporation of water from a one-phase system leading to a phase separation.

26. A method according to claim 25, wherein said evaporating process has a duration between 0,1 and 100 hours.

27. A method according to claim 25, wherein said evaporating process has a duration between 0,1 and 50 hours.

28. A method according to claim 25 to 27, wherein said evaporating process is carried out at a temperature between 0° C and 100° C.

29. A method according to claim 25 to 27, wherein said evaporating process is carried out at a temperature between 0° C and 50° C.

30. A method according to one of the claims 25 to 29, wherein said evaporating process is carried out under a pressure of 0,1 to 760 mm Hg p.

31. A method according to one of the claims 25 to 30, wherein said evaporating process is stopped when the water concentration within the system is between 5 to 80 %.

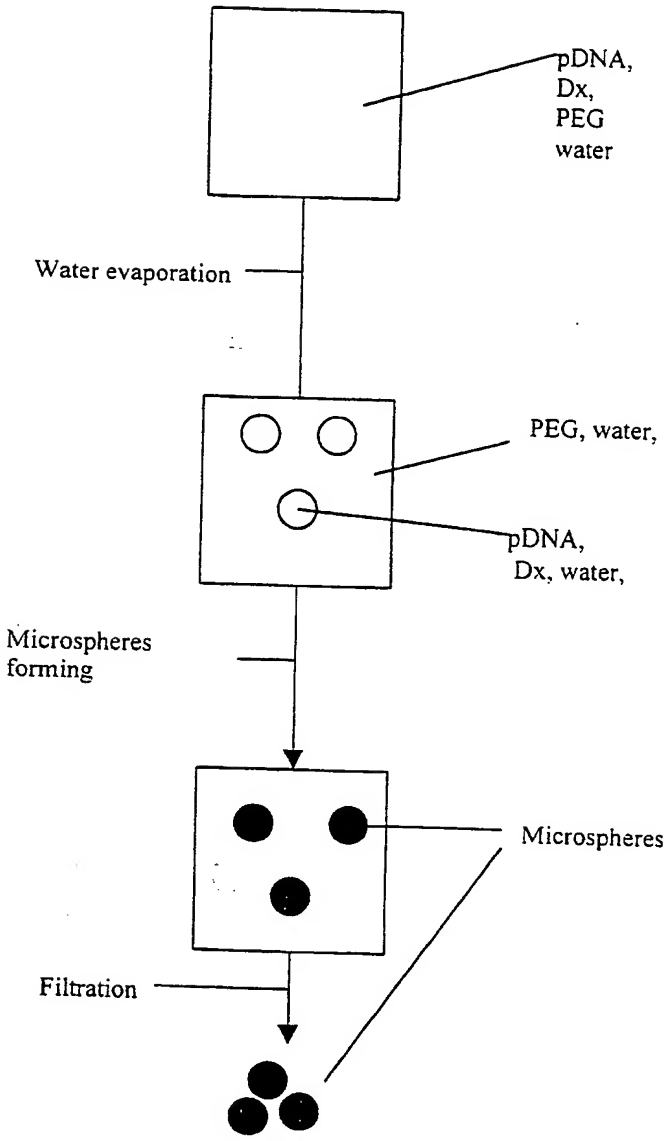
32. A method according to one of the claims 25 to 30, wherein said evaporating process is stopped when the water concentration within the system is between 5 to 75 %.

33. A method according to one of the claims 27, 29 or 31, wherein the calcium phosphate precipitation method is used.

34. A method of applying a composition according to one of the above claims 1 to 33 to a cell culture.

35. Microparticles being formed by conducting a method according to one of the claims 25 to 34.

36. Microparticles according to claim 35 being composed of at least 75 % polymer molecules and 25 % or less biological material.


pDNA,
Dx,
PEG
water
Water evaporation
PEG, water,
pDNA,
Dx, water,
Microspheres
forming
Microspheres
Filtration

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